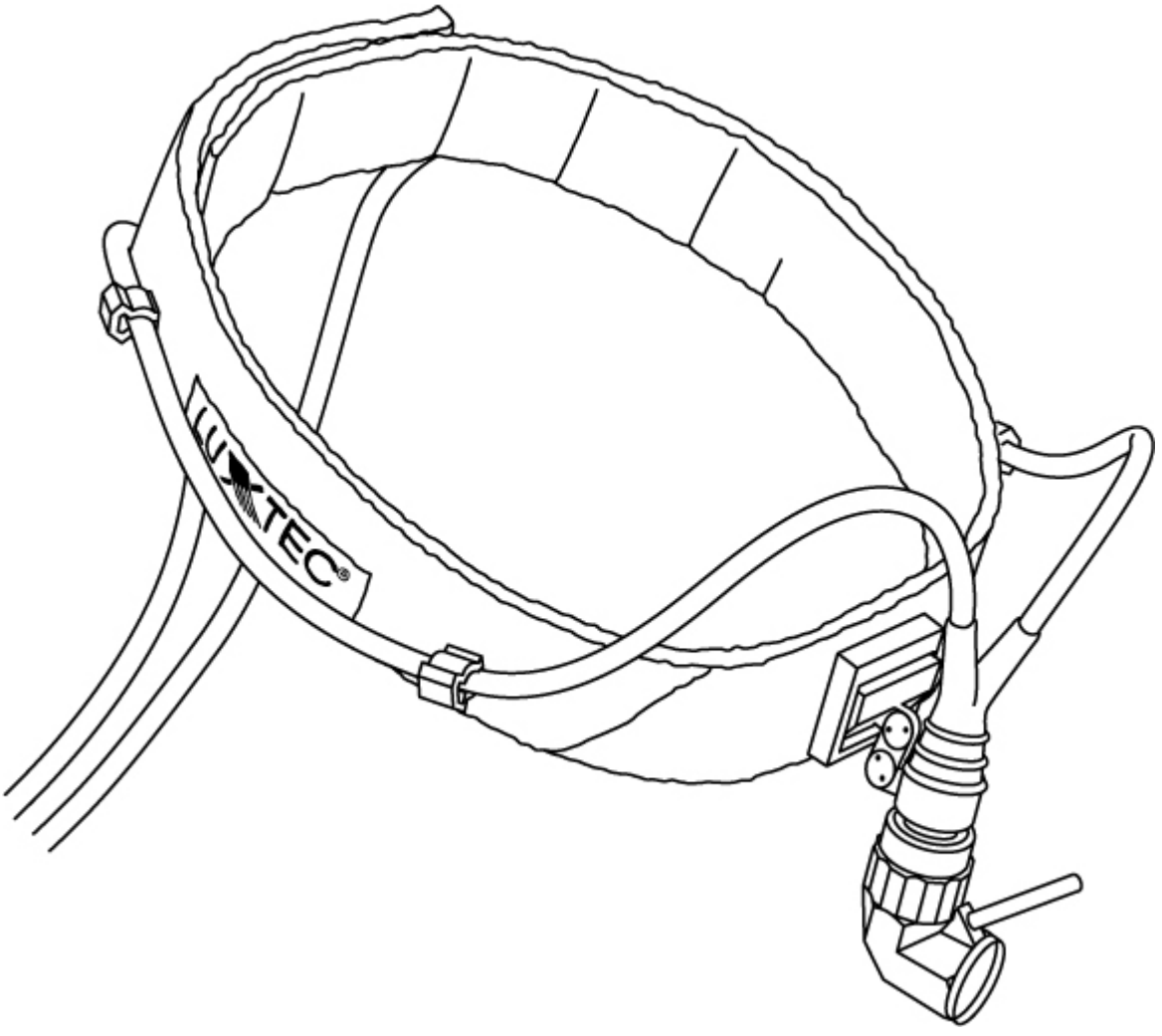
LUXTEC
A Division of LXU Healthcare, Inc.

UltraLite Headlight Operation and Service Manual



ENGLISH

TABLE OF CONTENTS

Indication for Use 2
General Warnings 2
Assembly 3-4
Adjustments 4-5
Replacement Part Numbers ... 5
Care and Maintenance 6
Troubleshooting 6
Luxtec Equipment Warranty 7
Luxtec Cable Warranty 7
Repair and Return 7

INDICATION FOR USE

This fiber optic light guide system is designed to deliver illumination from a high intensity light source to a surgical headlight for surgical site illumination, either standard or minimally invasive. While the cable light source endfittings are compatible with all light sources, brightness and spot quality vary with specific types of light sources. The xenon UltraLite systems perform best with Luxtec xenon light sources.

Any light source used with this cable should have a maximum output of 0.25W IR at the cable port to prevent cable and/or headlight damage during use.

GENERAL WARNINGS

The user of this product should be thoroughly familiar and trained in the use and care of this product.

The user should carefully study this manual before making any attempt to use the product clinically. Instructions should be followed specifically, with special attention given to warnings and cleaning instructions. This manual should also be available to the surgical team during a procedure.

Follow the instructions in the operating manuals of other manufacturer's equipment when they are use in conjunction with this product.

Before every procedure, carefully inspect the light guide cable to ensure it has been properly maintained, cleaned and sterilized (if compatible), and that it is fully functional.

Any light source used with this cable should have a maximum output of 0.25W IR at the cable port to prevent cable and/or headlight damage during use.

Light sources use high intensity lamps, which produce heat as well as brilliant light. The high brightness produced by the light source and the light output of the light guide cable can cause burns. Care should be taken to follow the maintenance and cleaning instructions. Excessive bending of the cable should be avoided.
Use care not to point the light guide directly at the eye while in operation. The brilliant light output can cause severe eye discomfort.

FIRE HAZARD: DO NOT DRAPE OR COVER THE LIGHT SOURCE OR THE LIGHT GUIDE WHILE IT IS OPERATING. DO NOT PLACE THE LIGHT GUIDE ON A DRAPE WHILE IT IS OPERATING.

CAUTION: The metal portions of the cable at the light source get hot during operation. Allow components to cool outside of the light source for at least 5 minutes before touching.

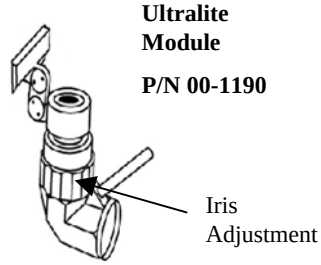
ASSEMBLY OF HEADLIGHT SYSTEMS

The Luxtec headlight assembly consists of a headlight with a variable spot module, a cushioned headband or sweatband, bifurcated fiber optic cable and two gown clips.

To assemble, attach the headlight module by sliding the bottom of the module clip into the module receptacle, then push the top in until it makes an audible ”snap” (Figure 1). To attach the joystick, thread it into the hole in the front of the headlight module.

To attach the fiber optic cable, insert the angled end of the cable into the headlight module until it snaps into place (Figure 2). A bifurcated cable fits into the cable clips on both sides and the rear of the headband or sweatband (Figure 3).

Figure 1a



Remove the cable from the module by grasping the body of the module in one hand and the lower-most ridges of the cable in the other hand and pulling them axially apart. Do not hold the cable by its leg(s) or strain relief.

Figure 1

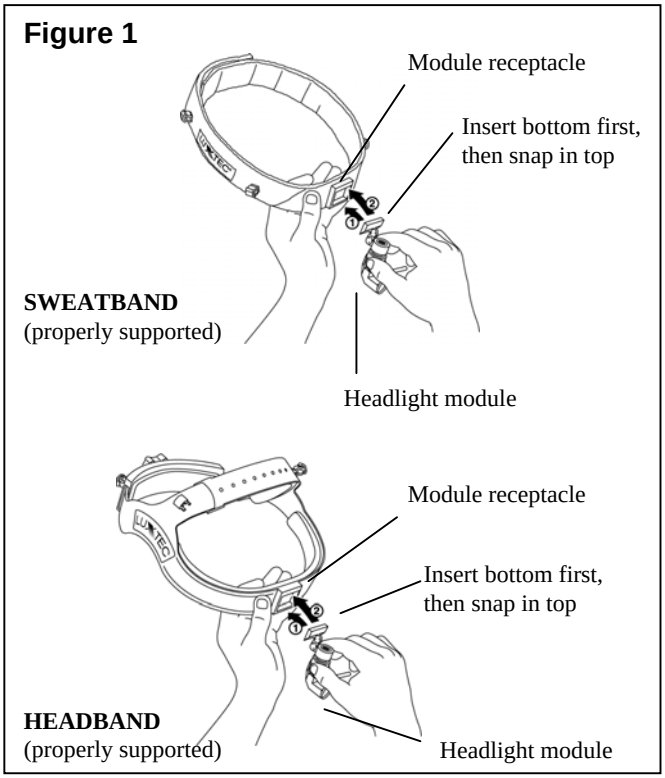
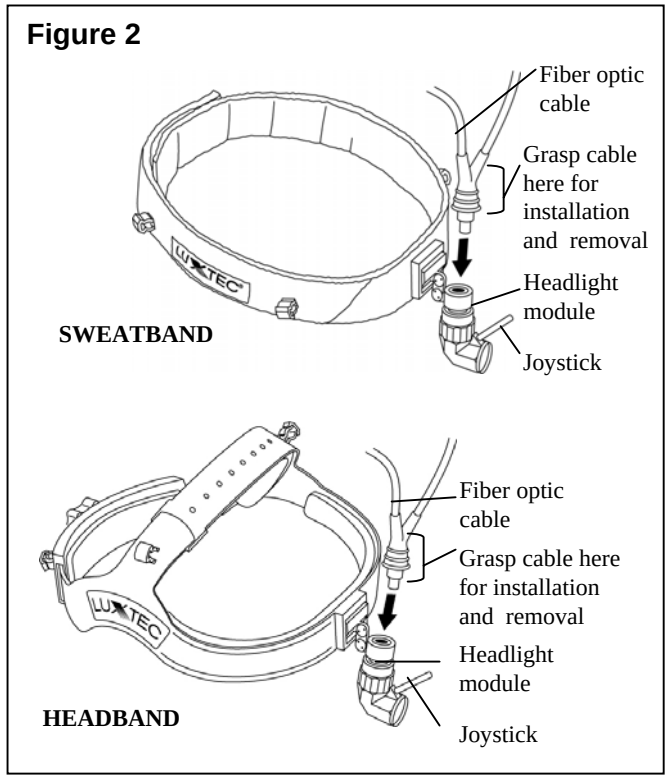


Figure 2

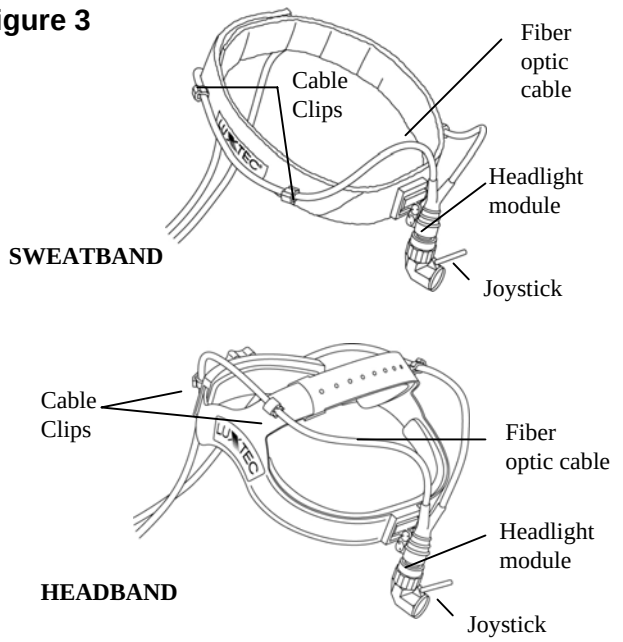


Remember, the cable is made of glass fibers. When adjusting the cable on the headband, do no bend the cable more than 60 degrees. The cable is designed to curve gently around the shape of the headband.

All illustrations are representative and may not reflect your actual model and accessories.

ASSEMBLY OF HEADLIGHT SYSTEMS

Figure 3



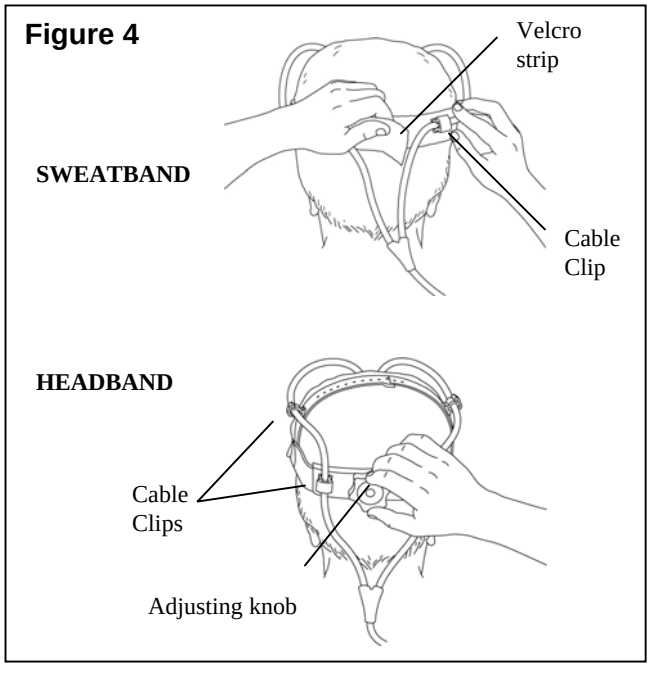
Next, place the headband or sweatband on your head. You can make size adjustments on the headband by turning the knob at the rear of the headband until it fits comfortably. The cross band can be adjusted for even more comfort. Push out the tab and slide the band until the fit is correct, then replace the tab. The sweatband should be pulled to a comfortable tension and closed using the velcro strip *(Figure 4)*.

To remove the module from the headband or sweatband, a small screwdriver is needed. Insert the screwdriver into the slot at the top of the module receptacle. Lift the handle of the screwdriver and the module will slide out.

Caution:

To plug or unplug the fiber optic cable from the light source, it is recommended that the light source power be turned off. Be sure to hold the strain reliever near the end of the cable. This part of the cable is reinforced to prevent damage to the glass fibers inside, and to prevent burns.

Figure 4



ADJUSTMENTS

Once the headlight module and fiber optic cable are attached to the headband, the headlight assembly is ready to use.

The headlight module can be adjusted while wearing the headlight system by grasping the joystick. The joystick can be removed for autoclaving or to prevent misaligning the headlight module when working in close quarters. The iris adjustment varies the spot size from 20mm to 100mm (0.8 to 4 inches) at a 40 cm (16 inch) working distance (*Figure 1a*).

The headlight system comes with two gown clips to relieve the weight of the cable from the headband. The upper clip is attached to the surgical gown just below the shoulder (*Figure 5*). Be sure to leave enough slack in the cable to allow for freedom of head movement. If the surgeon needs to detach the cable from the light source, the lower gown clip is used to attach to the surgeon's gown. This eliminates the risk of dropping or tripping over the cable.

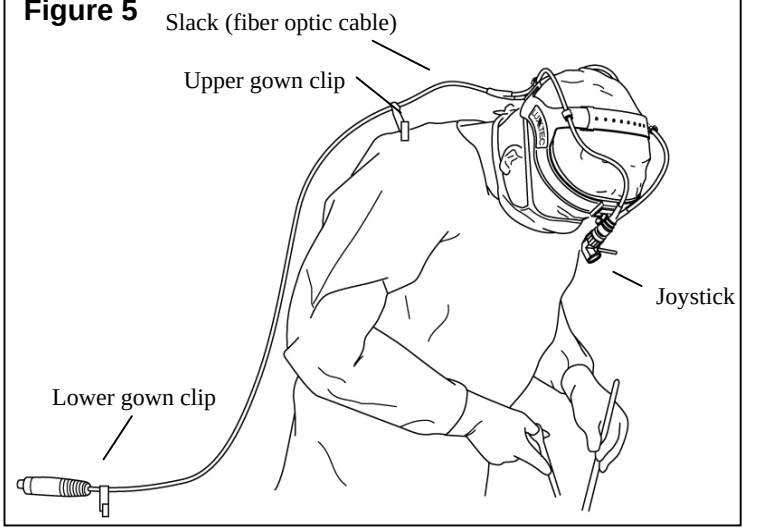
ADJUSTMENTS

CAUTION: The metal portions of the cable at the light source get hot during operation. Allow components to cool outside of the light source for at least 5 minutes before touching.

Luxtec manufactures its headlights to the highest quality standards. Each one is tested thoroughly before leaving the factory to ensure proper working conditions.

These instructions should help you get started with your new Luxtec equipment, quickly and easily. If you have any problems, please contact the Luxtec Service Department, (800) 325-8966, or (508) 835-9700, Fax (508) 835-9976.

Figure 5



REPLACEMENT PARTS

Part Number	Description
AX-1375-BIF	Headband with Ultralite 2 bifurcated cable, Ultralite module and extended linkage
AX-1385-BIF	Sweatband with Ultralite 2 bifurcated cable, Ultralite module and extended linkage
AX-1375-BIF-SL	Headband with Ultralite 2 bifurcated cable and Ultralite module
AX-1385-BIF-SL	Sweatband with Ultralite 2 bifurcated cable and Ultralite module
AX-1175-BIF	Headband with bifurcated cable, Ultralite module and extended linkage
AX-1185-BIF	Sweatband with bifurcated cable, Ultralite module and extended linkage
AX-1175-BIF-SL	Headband with bifurcated cable and Ultralite module
AX-1185-BIF-SL	Sweatband with bifurcated cable and Ultralite module
00-1170-BIF	Replacement headband for AX-1175-BIF or AX-1175-BIF-SL
00-1190	Module (gray)
00-1190-EL	Module (gray) with extended linkage
00-1270-BIF	Replacement headband for AX-1375-BIF or AX-1375-BIF-SL
00-1290	Sweatband for bifurcated cable
00-1290-BIF	Replacement sweatband for AX-1375-BIF or AX-1375-BIF-SL
00-2300-9	Replacement cable bifurcated (add –G for gray cable)
00-2900-9	Ultralite 2 bifurcated cable
400282	Replacement kit pad for headband
400286	Joystick for 00-1190, pack of 3

CARE AND MAINTENANCE

All Headlight Systems:
To ensure long life for the headband, cable, and modules, they should be stored in the duffel bag or case provided. Fiber optic cables are fine, high quality optical instruments. You can prolong the useful life by following a few guidelines:

- Avoid stretching your cable, forming configurations involving sharp angles or kinks, or contact with sharp or pointed objects. The internal light fibers are made of glass, a material which breaks under stress. Fiber breakage will result in diminished light output.
- Utilize the gown clips (If provided) to keep the headlight cable secured to the surgeon's gown for greater comfort and maneuverability. (This does not include endoscopic use)
- Do not use your fiber optic cable with any alterations to it's original design or fabrication. Bundle size (aperture) of the fiber optic cable should be matched to the aperture of the instrument to obtain maximum light output.
- NOTE: A larger aperture fiber optic cable will not increase light output of a smaller aperture instrument.
- Keep the optical faces from contacting the floor or other hard surfaces. The resulting scratches will diminish light output. Store the cables in sterilization trays for additional protection.
- Any inadvertent cut or puncture to the silicone tube will render the cable unsafe. It should be taken out of service immediately.

Cleaning Modules:
The headlight module may be wiped down with alcohol. The lens should be cleaned only with lens tissue available at any camera store. Follow the package directions.
Follow all applicable bloodborne pathogen cleaning procedures as indicated by OSHA and / or your hospital requirements when cleaning, disinfecting, and sterilizing instruments and accessories.

Cleaning Joystick (only):
The joystick can be removed from the module for autoclaving.

Cleaning Sweatband:
The sweatband may be cleaned using standard wash cycles in warm water and detergent. Air dry.

Cleaning Headband:
The headband may be cleaned by an alcohol wipedown or washed with lukewarm water and mild detergent. Rinse thoroughly with water.

Cleaning Cable:
Luxtec suggests that the use of alcohol wipes to clean the UltraLite and Sweatband headlight cables.

Disinfecting Cable:
Soaking the UltraLite 2 cables in any sterilizing disinfectant should be avoided. There is a lens assembly at the light source end, which is not sealed and could allow moisture to penetrate behind the lensing.

Sterilizing Cable:
The UltraLite fiber optic cable has not been specifically designed to withstand sterilization. There is a lens assembly at the light source end, which is not sealed and could allow moisture to penetrate behind the lensing.

WARNING: Do not autoclave the headband, cables, sweatband or headlight modules.

TROUBLESHOOTING

For additional technical assistance, please contact the Luxtec Service Department at 1-800-325-8966 (USA only) or +1-508-835-9700, Fax +1-508-835-9976 or email: info@luxtec.com

LUXTEC HEADLIGHT WARRANTY

Luxtec warrants that the equipment manufactured by Luxtec shall be free from defects in material and workmanship under normal use and service for a period of eighteen (18) months from the date of shipment from Luxtec. Luxtec's sole and exclusive liability under warranty shall be, at Luxtec's option, either to repair or replace any component which fails during the warranty period due to any defect in workmanship or material F.O.B. factory if:

1. Customer promptly reports such defect to Luxtec in writing,
2. If requested by Luxtec, customer returns equipment to Luxtec with shipping charges and,
3. Upon inspection, Luxtec finds the equipment to be defective.

This warranty is contingent upon normal and proper use of the equipment. It does not cover equipment modified without the written approval of Luxtec, subjected to unusual physical or electrical stress, or damaged during shipment. This warranty is non-transferable unless authorized in writing by Luxtec. Luxtec reserves the right to make design changes on its products without liability to incorporate said change in Luxtec products previously designed or sold.

Upon receipt of the product, it should be carefully inspected. If any defect is discovered, notification must immediately given to the manufacturer.

LUXTEC CABLE WARRANTY

LUXTEC warrants that the cables furnished hereunder shall be free from defects in material and workmanship under normal use and service for a period of eighteen (18) months from the date of shipment from LUXTEC. LUXTEC's sole and exclusive liability under this warranty shall be, at LUXTEC's option, either to repair or replace any components of the cable which fails during the warranty period due to workmanship or material F.O.B. factory if:

1. Customer promptly reports such a defect to LUXTEC in writing,
2. If requested by LUXTEC, customer returns equipment to LUXTEC with shipping charges pre-paid and,
3. Upon inspection, LUXTEC finds the cable to be defective.

This warranty is contingent upon normal and proper use of the cable and does not cover:

- Fiber Breakage,
- Soaking of cable lens in sterilizing disinfectant, or autoclaving,
- A cable which has been modified without the written approval of LUXTEC,
- A cable that has been subjected to unusual physical stress, or
- A cable that was damaged during shipment.

This warranty is non-transferable unless authorized in writing by LUXTEC.

If LUXTEC is unable to remedy any defect in the cable as required by the foregoing warranties, LUXTEC's liability shall in no event exceed the purchase price received hereunder by LUXTEC for the equipment.

THE WARRANTIES SET FORTH HEREIN ARE IN LIEU OF ANY OTHER REPRESENTATIONS OR WARRANTIES. LUXTEC DISCLAIMS AND CUSTOMER WAIVES ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING BUT NOT LIMITED TO, ALL IMPLIED WARRANTIES OR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL LUXTEC BE LIABLE TO ANY PARTY FOR INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER RELATED TO THIS OR ANY OTHER CLAIM, REGARDLESS OF ANY KNOWLEDGE OF LUXTEC OF SUCH POTENTIAL DAMAGES.

REPAIR AND RETURN

Any device must be clean when returned to LUXTEC. LUXTEC reserves the right to return unrepaired any equipment that is contaminated with blood or other organic material.

To obtain service under warranty or return product for repair, the customer should contact the local LUXTEC distributor or call LUXTEC Customer Service at 1-800-325-8966 (USA only) or +1-508-835-9700.

Warranty Service and Repair:

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Information contained in this manual is subject to change without notice.

Luxtec Corporation declares that this product meets the
Essential Requirements specified in Annex 1
of the Medical Device Directive (MDD).

CE

LUXTEC

Declaration of Conformity

Manufacturer's Name:	Luxtec Corporation
Manufacturer's Address:	99 Hartwell Street West Boylston, MA 01583 USA
Type of Equipment:	Medical Equipment – Surgical Headlight System

Application of Council Directive: Council Directive 93/42/EEC: Class I, Self-Declaration, Annex VII.

EU Classification: Rule 12, Annex IX

Standards to which conformity is declared: EN60601-1, EN60601-1-2

CE Mark first applied: 1998

Authorized European Representative:
Address:
Medical Products International Europe, B. V.
Schutweg 13 a
5145 NP Waalwijk, The Netherlands
Telephone: +31 (0)416 563 754
Fax: +31 (0)416 563 926

I, the undersigned, hereby declare that the equipment specified herein conforms with the applicable provisions of EC Directive 93/42/EEC concerning medical devices:

Signature: Thomas F. Bregani
Thomas F. Bregani, Quality Assurance Manager

Date of original Declaration: June 15, 1998
Date of this revision: February 18, 2002

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